DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M4963

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

December 8, 2000

Our Reference: 2951112

Masaru Ogihara, Vice President
JFC International, Inc.
540 Forbes Boulevard
South San Francisco, California 94080

WARNING LETTER

Dear Mr. Ogihara:

We inspected your seafood firm, Japan Fish Company, located at 699 Illinois Street, San Francisco, California, on August 7 and 8, 2000. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your fish and fishery products, specifically tuna, yellowtail, and sea urchin roe, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with Mr. Mitsuru Fujikiwa, Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your ready reference. Your serious HACCP violations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for Ready-to-eat raw sea urchin roe to control the food

safety hazard of pathogen growth and toxin formation due to time and temperature abuse.

2. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for Yellowtail or Amberjack does not list the food safety hazard of *Clostridium botulinum* for the vacuum packaged (airtight) product you receive.

3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations regarding the adequacy of ice at the Receiving and Cooler Storage critical control points (CCPs), to control the food safety hazard of histamine formation listed in your tuna and Yellowtail or Amberjack HACCP plans.

4. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm performed an affirmative step of maintaining foreign processor's HACCP plans and Letters of Guarantee for tuna and amberjack products manufactured by [redacted] and [redacted] that were not adequate. Specifically, the HACCP plans of the firms do not provide sufficient controls for the hazards associated with the products being imported due to the following:

a) The foreign processor, [redacted], does not list histamine formation as a hazard in their Fresh Tuna H & G HACCP plan.

b) The foreign processor, [redacted], does not list *Clostridium botulinum* and ciguatera as hazards in their HACCP plan for the vacuum packed Yellowtail or Amberjack they process.

The above violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure, injunction, or detention without physical examination of future shipments of imported products.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. If you cannot complete all the corrections before you respond, we expect

that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Davina M. Watson

for Dennis K. Linsley
Director
San Francisco District

Enclosure

cc: VIA FEDERAL EXPRESS
Ms. Tsuyako Takahagi
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